



APR 6 2006

**510(k) SUMMARY**

**Submitter:** Zimmer Spine, Inc.  
7375 Bush Lake Road  
Minneapolis, MN 55439

**Company Contact:** Tim Crabtree  
Senior Regulatory Affairs Specialist

**Date Prepared:** February 14, 2006

**Device Name:** Trade Name: Dynesys® Spinal System  
Common Name: Spinal Fixation System.

**Classification Name:** Posterior Metal/Polymer Spinal System, Fusion

**Classification:** 21 CFR §888.3070, Pedicle screw spinal system

**Class:** II

**Product Code:** NQP

**Predicate Devices:** Dynesys® Spinal System (K031511, K043565)

**Description of Device:** The Dynesys Spinal System is comprised of a variety pedicle screws sizes, tensioning cords and longitudinal spacers that are uniquely fitted for each individual case. The pedicle screws are manufactured from medical grade titanium alloy. The tensioning cords are manufactured from Sulene-PET (polyethylene-terephthalate). The longitudinal spacers are manufactured from Sulene-PCU (polycarbonate-urethane). The pedicle screws are provided with or without hydroxyapatite coating.

**Intended Use:** When used as a pedicle screw fixation system in skeletally mature patients, the Dynesys Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of

the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, and failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the Dynesys Spinal System is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;
- Who are having the device fixed or attached to the lumbar or sacral spine;
- Who are having the device removed after the development of a solid fusion mass.

#### **Comparison of Technological Characteristics:**

Testing and analysis of proposed hydroxyapatite coated pedicle screw components for the *Dynesys* Spinal System was performed. The results of this testing demonstrated that there are no fundamental technological differences between the proposed hydroxyapatite pedicle screws and the pedicle screw components of the current *Dynesys* Spinal System.

#### **Substantial Equivalence:**

The hydroxyapatite coated pedicle screws of *Dynesys* Spinal System are substantially equivalent to the original *Dynesys* Spinal System pedicle screw components based on intended use, design, and function.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 6 2006

Zimmer Spine, Inc.  
c/o Mr. Tim Crabtree  
Senior Regulatory Affairs Specialist  
7375 Bush Lake Road  
Minneapolis, Minnesota 55439

Re: K060638

Trade/Device Name: Dynesys® Spinal System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: Class II  
Product Code: NQP  
Dated: March 9, 2006  
Received: March 10, 2006

Dear Mr. Crabtree:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Tim Crabtree

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number: Pending K060638

Device Name: Dynesys® Spinal System

**Indications for Use:** When used as a pedicle screw fixation system in skeletally mature patients, the *Dynesys* Spinal System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, and failed previous fusion (pseudarthrosis).

In addition, when used as a pedicle screw fixation system, the *Dynesys* Spinal System is indicated for use in patients:

- Who are receiving fusions with autogenous graft only;
- Who are having the device fixed or attached to the lumbar or sacral spine;
- Who are having the device removed after the development of a solid fusion mass.

(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K060638

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)